

Exhibit D

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products
Liability Litigation,

No. MDL15-2641-PHX-DGC

Doris Singleton Jones, an individual,

Plaintiff,

v.

C. R. Bard, Inc., a New Jersey corporation;
and Bard Peripheral Vascular, Inc., an
Arizona corporation,

Defendants.

DEFENDANTS' PROPOSED JURY INSTRUCTIONS

DATED: May 1, 2018

**DEFENDANTS' PROPOSED INSTRUCTION STRICT LIABILITY
DESIGN**

Mrs. Jones contends that Bard is strictly liable because of a defective design of the ECLIPSE IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of a defect in the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable. To recover damages for strict product liability based on a design defect, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the product was defectively designed;

Second, the design defect existed at the time the product left the control of Bard;
and

Third, the design defect in the product was a proximate cause of Mrs. Jones' injury.

There is not a single general way to define what constitutes a design defect in a product. Whether or not a product is defective is a question of fact to be determined by you, the jury, based on the instruction that I will give you and the evidence that has been received during the trial.

Although Bard is not required to ensure that a product design is incapable of producing injury, it has a duty to exercise reasonable care in choosing the design for a product.

To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a product design against the utility or benefits of that product design. You must decide whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including the following factors:

- 1) the usefulness of the product;
- 2) the severity of the danger posed by the design;

- 3) the likelihood of that danger;
- 4) the avoidability of the danger, considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of warnings, and common knowledge or the expectation of danger;
- 5) the user's ability to avoid the danger;
- 6) the technology available when the product was manufactured;
- 7) the ability to eliminate the danger without impairing the product's usefulness or making it too expensive;
- 8) the feasibility of spreading any increased cost through the product's price;
- 9) the appearance and aesthetic attractiveness of the product;
- 10) the product's utility for multiple uses;
- 11) the convenience and durability of the product;
- 12) alternative designs of the product available to the manufacturer; and
- 13) the manufacturer's compliance with industry standards or government regulations.

In determining whether a product was defectively designed, you may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized Mrs. Jones' injury. In determining the reasonableness of the product design chosen by Bard, you should consider:

- 1) the availability of an alternative design at the time Bard designed this product;
- 2) the level of safety from an alternative design compared to the actual design;
- 3) the feasibility of an alternative design, considering the market and technology at the time the product was designed;
- 4) the economic feasibility of an alternative design;

- 5) the effect an alternative design would have on the product's appearance and utility for multiple purposes; and
- 6) any adverse effects on Bard or the product from using an alternative design.

In determining whether a product was defective, you may consider proof of a manufacturer's compliance with federal or state safety and non-safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

In deciding whether the design of the ECLIPSE filter was defective, you may also consider whether the FDA instituted regulatory action with respect to the ECLIPSE filter. However, a product may be defective even if the FDA institutes no regulatory action.

If you decide that the risk of harm in the product's design outweighs the utility of that particular design, then the manufacturer exposed the consumer to greater risk of danger than the manufacturer should have in using that product design, and the product is defective. If after balancing the risks and utility of the product, you find by a preponderance of the evidence that the product suffered from a design defect that proximately caused Mrs. Jones' injury, then Mrs. Jones is entitled to recover.

Plaintiff's Objection:

The instruction places undue emphasis on FDA evidence, focusing the jury's attention on FDA action or inaction on three separate occasions.

Defendants' Response:

This is the instruction given in *Booker* with only the name and product name changed. As is stated in Defendants' objection to Plaintiff's proposed instruction, Plaintiff deleted two necessary elements from the instruction, the Georgia Pattern Instruction on compliance with industry standards and the language reflecting Georgia law regarding regulatory action. Defendants incorporate their objection to Plaintiff's proposed instruction on strict liability design.

DEFENDANTS' PROPOSED INSTRUCTION NEGLIGENT DESIGN

Mrs. Jones claims that Bard was negligent in the design of the ECLIPSE IVC filter she received. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

- (1) Bard had a duty of reasonable care to Mrs. Jones,
- (2) Bard breached that duty in the design of the ECLIPSE filter,
- (3) the breach was a proximate cause of Mrs. Jones' injury, and
- (4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances. In making the determination of whether Bard acted reasonably, you should consider the risk-benefit analysis for design defect about which I previously instructed you.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in the design of the ECLIPSE filter she received.

Plaintiff's Objection:

Plaintiff proposes that the instruction from Booker be given, with name and product information modified. Bard's proposed language would confuse the negligent design instruction with the strict product liability instruction making risk/benefit a de facto element of both claims and unnecessarily emphasizing this aspect of the claim.

Defendants' Response:

Defendants request that this language be added to make the instruction consistent with Georgia law. See, *Ogletree v. Navistar International Transportation Corporation*, 271 Ga. 644 (1999), in which the Georgia Supreme Court held, "In a negligent design case, the risk-utility analysis applies to determine whether the manufacturer is liable. Thus, the mandate that a product's risk must be weighed against its utility incorporates the concept of "reasonableness" so as to apply negligence principles in the determination of whether the manufacturer defectively designed its product. (Citations omitted)"

**DEFENDANTS' PROPOSED INSTRUCTION NEGLIGENT FAILURE TO
WARN**

Mrs. Jones claims that Bard was negligent in failing to warn Dr. Avino about the risks of the ECLIPSE IVC filter he implanted in Ms. Jones. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

- (1) Bard had a duty of reasonable care to Mrs. Jones,
- (2) Bard breached that duty in the adequacy of the warnings about the ECLIPSE filter provided to Dr. Avino,
- (3) the breach was a proximate cause of the her injury, and
- (4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances. In making the determination of whether Bard acted reasonably in warning Dr. Avino, you should consider the same factors for strict liability failure to warn about which I previously instructed you.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in failing to warn about the risks of the ECLIPSE filter she received.

Plaintiff's Objection:

Plaintiff objects only to the highlighted text. The proposed reference back to the strict liability instruction will be confusing to the jury since it would send the message that it is deciding the same issue for both claims when such claims are separate and distinct. *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999).

Defendant's Response:

Defendants request these revisions to the instruction given in *Booker* to comply with Georgia law. Under Georgia law, whether premised on negligence or strict liability, Plaintiff must prove that "Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its filter. *Shelton v. GALCO Int'l*,

Ltd., No. 3:16-CV-00033-TCB, 2017 WL 3597497 (N.D. Ga. July 19, 2017) (quoting *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)) (“[T]he duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of the product.”). Further, Plaintiff’s reliance on *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999) is misplaced. While the Georgia Courts acknowledge that there are two separate causes of action, they also recognize that the same duty based elements apply to both strict liability and negligent failure to warn. J. Kennard Neal and Catherine Payne, *Ga. Products Liability Law* § 8:1 (4th ed. 2018) (“Georgia has traditionally recognized failure to warn claims arising both in negligence and in strict liability. [H]owever, Georgia courts make no distinction between the two, but apply the same duty concepts and the same tripartite test of foreseeability.”) (citations omitted); *Id.* at § 2:1 (“[I]n examining either type of claim, Georgia courts have consistently applied the same duty-based negligence analysis.”)

Also, and importantly, the instruction as previously written is confusing because it refers to a duty to the “Plaintiff,” but in the context of a medical device the duty is to the implanting physician. *McCombs v. Synthes*, 277 Ga. 252, 253, 587 S.E.2d 594 (2003). If learned intermediary is not included in both the strict liability and negligent failure to warn instructions, Defendants request that it be given as a separate instruction as set forth below.

LEARNED INTERMEDIARY

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient’s doctor, who acts as a learned intermediary between the patient and the manufacturer.

McCombs v. Synthes, 277 Ga. 252, 253, 587 S.E.2d 594 (2003)

**DEFENDANTS' REQUEST FOR INSTRUCTION
FAILURE TO READ WARNING**

If a physician does not actually read a warning provided by the manufacturer of a medical device, the adequacy or lack of adequacy of that warning cannot be the proximate cause of the plaintiff's injuries.

Plaintiff's Objection:

This instruction is unnecessary and improper. Questions of causation are for the jury. In addition, Bard had a continuing duty to warn of dangers under Georgia law. Issuance of post-implantation warnings could have allowed for retrieval of Mrs. Jones' filter before it fractured. Ga. Code Ann., Section 51-1-11(C). Further, the instruction is an improper comment on the evidence. It also will be confusing since Dr. Avino testified that he read the IFUs for Bard devices and, even if a jury assumes they are predecessor devices, the warnings are the same for the Eclipse IFU.

Defendants' Response:

Under Georgia law, the failure to warn claim can be based on either the adequacy of the warning or the adequacy of the attempts to communicate the warning. Failure to read a warning prevents recovery on the first part of the claim. "[F]ailure to read instructions or printed warnings will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the product's potential risk." *Wilson Foods Corp. v. Turner*, 218 Ga. App. 74, 75, 460 S.E.2d 532, 534 (1995); *Camden Oil Co., LLC v. Jackson*, 609 S.E.2d 356, 358 (Ga. App. 2004) ("where a plaintiff does not read an allegedly inadequate warning, the adequacy of the warning's contents cannot be a proximate cause of the plaintiff's injuries"). The evidence in the case is that the Eclipse IFU contains different (and contained additional) warnings than the predecessor devices.

**DEFENDANTS' REQUEST FOR INSTRUCTION
JURY DELIBERATION; PRODUCT DEFECT**

If you find by a preponderance of the evidence that the product was defective in design or the adequacy of the warning provided when it left the control of the manufacturer and that the plaintiff's injury was proximately caused by that defect, then you would return a verdict for the plaintiff, unless the plaintiff is denied recovery under some other principle of law given to you in these charges.

If after considering all the evidence, you do not believe by a preponderance of the evidence that the product by which plaintiff claims to have been injured was defective in design or adequacy of the warning when it left the manufacturer's control or that the product was the proximate cause of the plaintiff's injury, then you would end your deliberations; the plaintiff would not be entitled to recover; and you would return a verdict for the defendant.

Georgia Pattern Instruction 62.720 Jury Deliberation; Product Defect

Plaintiff's Objection:

This instruction is unnecessary in light of other final instructions given to the jury. In addition, it is confusing and risks having the jury believe that it must find for Plaintiff on all claims to render a verdict (or both design or both warning claims). There are *four* separate claims and a jury need only find for Plaintiff on *one* of these claims. This instruction muddles that fact.

Defendants' Response:

This is a Georgia pattern instruction that is not encompassed in the instructions as given and provides the jury with necessary guidance on how to proceed during their deliberations.

DEFENDANT'S PROPOSED INSTRUCTION DAMAGES

It is the duty of the court to instruct you about the measure of damages. By instructing you on damages, I do not mean to suggest for which party your verdict should be rendered.

If you find for Mrs. Jones on any or all of her claims, you must determine her damages. Mrs. Jones has the burden of proving damages by a preponderance of the evidence. It is for you to determine what damages, if any, have been proved. Your award must be based on evidence and not on speculation, guesswork or conjecture.

Damages are given as pay or compensation for injury done. Where one party is required to pay damages to another, the law seeks to ensure that the damages awarded are fair to both parties. If you find by a preponderance of the evidence that Mrs. Jones is entitled to recover damages, you should award to Mrs. Jones such sums as you believe are reasonable and just in this case.

Necessary expenses resulting from the injury are a legitimate item of damages. As to medical expenses, such as hospital, doctor, and medicine bills, the amount of the damage would be the reasonable value of such expense as was reasonably necessary.

Mrs. Jones seeks to recover not only for her past medical expenses, but also for medical expenses that may be incurred in the future. If you find that the evidence shows with reasonable certainty that Mrs. Jones will sustain future medical expenses proximately caused by the actions of Bard, and if you find that the evidence shows with reasonable certainty the amount of such future medical expenses, Mrs. Jones would be entitled to recover those amounts, reduced to present cash value.

Pain and suffering are recoverable as damages. The measure of damages for pain and suffering is left to the enlightened conscience of fair and impartial jurors. Questions of whether, how much, and how long Mrs. Jones has suffered or will suffer are for you to decide.

Pain and suffering include mental suffering, but mental suffering is not recoverable as damages unless there is also physical suffering. In evaluating Mrs. Jones' pain and suffering, you may consider the following factors, if proven:

- (1) interference with normal living;
- (2) interference with enjoyment of life;
- (3) impairment of bodily health and vigor;
- (4) fear of extent of injury;

- (5) shock of impact;
- (6) actual pain and suffering, past and future;
- (7) mental anguish, past and future; and
- (8) the extent to which Mrs. Jones must limit activities.

If you find that Mrs. Jones' pain and suffering will continue into the future, you should award such damages for future pain and suffering as you believe Mrs. Jones will endure. In making such an award, your standard should be your enlightened conscience as impartial jurors. You may take into consideration the fact that Mrs. Jones is receiving a present cash value award for damages not yet suffered.

Plaintiff's Objection:

This instruction omits an important paragraph advising the jury that Bard must take the Plaintiff as it finds her and is not relieved of liability by virtue of any pre-existing conditions Plaintiff has. The Booker instruction adequately addresses this situation and merely sets forth a correct statement of the law.

Defendants' Response:

Defendants deleted and object to the last paragraph of the instruction given in *Booker* as not conformed to the evidence in this case. There is no evidence or testimony that any actions of Bard caused or contributed to Ms. Jones' existing medical conditions.

**DEFENDANTS' REQUEST FOR INSTRUCTION
TORT DAMAGES; DUTY TO LESSEN**

When a person is injured by the negligence of another, she must mitigate her damages as much as is practicable by the use of ordinary care and diligence.

If you find that plaintiff has suffered damages as alleged, under the law, she is bound to reduce those damages, as much as is practicable, by the use of ordinary care. If you believe that by the use of such care that she could have reduced the damages, you would determine to what extent and reduce such damages to that extent.

Georgia Pattern Instruction 66.015 Tort Damages; Duty to Lessen

Plaintiff's Objection:

There is no evidence supporting Mrs. Jones' alleged failure to mitigate her damages. Thus, instructing the jury on this issue will be confusing and contrary to the evidence. See also Plaintiff MILs 1-3.

Defendants' Response:

Plaintiff claims several alleged injuries for which she has received medical care and instruction that she has failed to follow. To the extent that she attributes those to the filter, her failure to follow medical advice or seek medical attention is relevant. O.C.G.A. §51-12-11; *Mallock v. Kicklighter*, 10 Ga. App. 605 (1912).

DEFENDANTS' PROPOSED INSTRUCTION A – PUNITIVE DAMAGES

Members of the jury, you have decided that Mrs. Jones should be awarded punitive damages. In order to determine the amount of punitive damages, the parties have presented evidence and will now present brief arguments.

The measure of punitive damages is your enlightened conscience as an impartial jury. Any award you make should be both reasonable and just in light of your previous award of compensatory damages, the conduct and circumstances of Bard, and the purpose of punitive damages.

In considering the amount of punitive damages, you may consider the following factors:

- 1) the nature and reprehensibility of Bard's conduct;
- 2) the extent and duration of Bard's wrongdoing and the likelihood of its recurrence;
- 3) the intent of Bard in committing the wrong;
- 4) the profitability of Bard's wrongdoing in Georgia;
- 5) the amount of compensatory damages you have previously awarded;
- 6) the financial circumstances, that is, the financial condition or the net worth of Bard based on the sale of Eclipse filters in Georgia.

In making an award of punitive damages, you should consider the degree of reprehensibility of Bard's wrongdoing. You should consider all of the evidence, both aggravating and mitigating, to decide how much punishment, penalty, or deterrence Bard's conduct deserves in the form of punitive damages. In assessing reprehensibility, you may consider whether:

- 1) the harm caused was physical, as opposed to economic;
- 2) the conduct showed an indifference to or a reckless disregard of the health or safety of others; and
- 3) the conduct involved repeated actions or was an isolated incident.

You may have heard evidence of other conduct and procedures of Bard. For the purpose of punitive damages, you may not consider evidence of any conduct of Bard that

is dissimilar to that which resulted in Mrs. Jones' injury – unless such dissimilar conduct was related to the specific harm suffered by Mrs. Jones in this case.

Plaintiff's Objection:

Neither *State Farm* nor *Gore* limit damages to sales of a product in a particular state. Trial Tr. at 2587. Moreover, Georgia law relating to punitive damages specifically states that there shall be “no limitation” on the amount a jury can award for punitive damages. O.C.G.A. § 51-12-5.1. The concern expressed by the Supreme Court concerning out of state conduct is to ensure that it (1) is not legal in other states and (2) bears some relationship to the conduct at issue in the case. *State Farm*, 538 U.S. at 421-23.

Defendants' Response:

Defendants request these changes to the instruction given in *Booker* comply with the US Supreme Court decisions on punitive damages. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996); *Dimaso v. Ford Motor Company, et. al.*, No. 99-A-6172-6, 2003 WL 22850075, at *1 (Ga. Super. 2003); *Hockensmith v. Ford Motor Co.*, No. 1:01-CV-3645G, 2003 WL 25639639, at *10 (N.D. Ga. Apr. 17, 2003). See also Georgia Suggested Pattern Jury Instructions, Vol. I: Civil Cases, No. 66.770-66.780 (5th ed. 2016).